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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LIU, SAMUEL W	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/930,329	TURPEN, THOMAS H.	
	Examiner	Art Unit	
	Samuel W Liu	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-36* is/are pending in the application.

4a) Of the above claim(s) *none* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12-23-03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

Claims 26-36 are pending.

Applicants' amendment filed 23 December 2003, which amends claims 26, 30 and 34, cancels claims 1-25, and adds claim 36 has been entered. Also, applicant's request (filed 23 December 2003) for extension of time of one month has been entered.

The following Office Action is applicable to the pending claims 26-36.

Please note that grounds of objection and/or rejection not explicitly restated and/or set forth below are withdrawn.

IDS

The references listed in IDS filed 23 December 2003 and IDS filed 26 January 2004 have been received and considered.

Claim Rejections - 35 USC § 112, the first paragraph

The rejection under 35 USC 112, the first paragraph – written description, is withdrawn in view of that reference 57 provided by applicant's IDS (filed 26 January 2003) has provided working example in this regard, and that the instant application describes use of self-cleaving ribozyme for transcriptional termination process at pages 12 and 15 of the specification.

Claim Rejections - 35 USC § 112, the second paragraph

Claims 26-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 recites "a replicon having a plus sense , RNA viral replication and ..." (line 4 of the claim); the recitation is indefinite because the phrase "a plus sense" appears to be incomplete and because it unclear as to whether or not the said plus sense refers to a DNA sequence or RNA sequence. The dependent claims are also rejected.

Claim Rejection –Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Claims 26-28 and 30-36 are rejected under the judicially created doctrine of the obviousness-type double patenting of claims 10-12 of US Pat. No. 5889191. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 10 of 5889191 and claims 26 and 28 of the instant application disclose the common subject matter, i.e., a method of expressing a foreign product in plants comprising (a) integrating a transgene into a chromosome of a plant cell for transcribing the transgene

comprising a replicon which comprises: a plus strand RNA plant virus-derived *replication origin* for replicating the replicon, and at least one foreign polynucleotide sequence (non-native to the plus strand RNA), a helper virus (note that the replicon is a RNA sequence generated from transcribing the transgene (see column 5, lines 57-62) with host RNA polymerase II (see column 7, lines 7-8); (b) providing the plant cell with the a helper virus comprising a gene encoding a plant RNA virus *replicase* that is necessary for the replicon function *via* infecting the plant with the helper virus; and (c) producing the additional replicon component, i.e., the movement protein via translating the mRNA (i.e., the component of the replicon that is of RNA sequence) that directs synthesis of the movement protein. The above disclosure of 5889191 meets all the limitation set forth in the application claims 26, 28 and 30. Claims 11-12 of 5889191 also sets forth the transected plant cell is comparable to the tobamovirus (TMV) for producing gene product, i.e., the functional movement protein, which meets the limitation of the instant claim 35. Thus, claims 10-12 of 5889191 are obvious variation of claims 26, 28, 30 and 35 of the current application.

Claim 10 of 5889191 sets forth a method for introducing the transgene into the subject plant via transformation wherein introducing the transgene is done by known transformation (see column 7, line 34) with growing the subject plant to an optimal condition prior to introducing the helper virus (see also column 7, lines 36-39). Thus, claim 10 of patent 5889191 is an obvious variation over claim 27 of the instant application.

Claim 10 of 5889191 is an obvious variation over claims 31-32 of the instant application since the claimed invention of 5889191 is directed to the method of over expressing gene products in plants which include antisense RNA, ribozyme RNA, regulatory enzyme, structural

protein, regulatory protein, or therapeutic protein wherein typical therapeutic proteins include members of the interleukin family of proteins and colony stimulating factors (see also column 7, lines 41-50).

Claims 10-11 of 5889191 disclose a functional movement protein encoded by the sequence of the replicon upon which the helper virus depends (see also column 6, lines52-54), which is the common subject matter set forth in claim 33 of the current application.

Since 5889191 disclosure sets forth that sequence of functional movement protein (depending on the said replicon) enables *systemic* infection thereby *systemic* expression of foreign gene product in the whole plant with the said helper virus (see column 6, lines 54-61), claims 10-11 of 5889191 is an obvious variation of claim 36 of the instant application.

Claims 10-12 of 5889191 are obvious variations over claims 33-34 of the instant application because claims 10-11 of 5881919 sets forth the replicon encodes the functional movement protein which the helper virus does not encode (see claim 10) and the function of the helper virus depends on the movement protein (see also column 6, lines 52-54), and because 5889191 invention is directed to the method for systemic infection of subject plant and systemic expression of the gene product (see the patent abstract and column 15, lines 10-12).

Therefore, the claims stated above in the instant application and those in US Pat. No. 5889191 discloses the same and/or common subject matter.

Claims 26-28 and 30-36 are rejected under the judicially created doctrine of the obviousness-type double patenting of claims 13-19 of US Pat. No. 6462255. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 13-17 of 6462255 and the instant claims 26, 28 and 30 discloses the common subject matter, i.e., a method of expressing a foreign product in plants comprising (a) integrating a transgene into a chromosome of a plant cell for transcribing the transgene comprising a replicon which comprises: a plus strand RNA plant virus-derived *replication origin* for replicating the replicon, and at least one foreign polynucleotide sequence (non-native to the plus strand RNA), a helper virus (note that the replicon is a RNA sequence generated from transcribing the transgene (see column 6, lines 10-15) with host RNA polymerase II (see column 7, lines 25-27); (b) providing the plant cell with the a helper virus comprising a gene encoding a TMV-derived *replicase* that is necessary for the replicon function (see claim 21) *via* infecting the plant with the helper virus; and (c) producing the additional replicon component, i.e., the movement protein via translating the mRNA (i.e., the component of the replicon that is of RNA sequence) that directs synthesis of the movement protein. The above disclosure of 6462255 meets all the limitation set forth in the application claims 26, 28 and 30. Claims 18-19 of 6462255 sets forth the transected plant cell is susceptible to the tobamovirus (TMV) for producing gene product, i.e., the movement protein, which meets the limitation of the instant claim 35. Thus, claims 13-19 6462255 are obvious variation of claims 26, 28, 30 and 35 of the current application.

Claim 13 of 6462255 sets forth a method for introducing the transgene into the subject plant wherein introducing the transgene is done by known transformation (see column 7, line 54) with growing the subject plant to an optimal condition prior to introducing the helper virus (see also column 7, lines 54-59). Thus, claim 10 of patent 6462255 is an obvious variation over the instant claim 27.

Claim 10 of 6462255 is an obvious variation over claims 31-32 of the instant application since the claimed invention of 6462255 is directed to the method of over expressing gene products in plants which include antisense RNA, ribozyme RNA, regulatory enzyme, structural protein, regulatory protein, or therapeutic protein wherein typical therapeutic proteins include members of the interleukin family of proteins and colony stimulating factors (see also column 7, lines 60-67).

Claims 13-19 of 6462255 disclose the functional movement protein encoded by the sequence of the replicon upon which the helper virus depends (see also the patent claims 4-5), which is the common subject matter set forth in claim 33 of the current application.

Claim 13 of 6462255 sets forth that the said replicon has characteristics of claims 1-7 which teach that the viral movement protein is capable of causing systemic expression of said replicon (see claim 7). Thus, claims 13-19 of 646255 are obvious variation of claim 36 of the instant application.

Claims 14 and 15 of 6462255 are obvious variations over claim 34 of the instant application because claim 14 discloses that the helper virus depends upon the replicon and claims 15 sets froth that the function of the helper virus depends *in trans* on expression of functional movement protein encoded by the replicon which causes systemic expression of said replicon (see the patent claims 1 and 7). Note that the method the patent claims 13-19 disclose the replicon which properties and biological functions are described in the patent claim 1 and 7.

Therefore, the claims stated above in the instant application and those in US Pat. No. 6462255 discloses the same and/or common subject matter.

Claims 26-28 and 30-36 are rejected under the judicially created doctrine of the obviousness-type double patenting of claims 11-16 of US Pat. No. 5965794. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 26, 28 and 30 of the instant application and claims 11-14 of 5965794 disclose the common subject matter, i.e., a method of expressing a foreign product in plants comprising (a) integrating a transgene into a chromosome of a plant cell for transcribing the transgene comprising a replicon which comprises: a plus strand RNA plant virus-derived *replication origin* for replicating the replicon, and at least one foreign polynucleotide sequence (non-native to the plus strand RNA), a helper virus (note that the replicon is a RNA sequence generated from transcribing the transgene (see column 6, lines 4-9) with host RNA polymerase II (see column 7, lines 22-23); (b) providing the plant cell with the a helper virus comprising a gene encoding a TMV-derived *replicase* that is necessary for the replicon function *via* infecting the plant with the helper virus; and (c) producing the additional replicon component, i.e., the movement protein via translating the mRNA (i.e., the component of the replicon that is of RNA sequence) that directs synthesis of the movement protein. The above disclosure of 5965794 meets all the limitation set forth in the application claims 26, 28 and 30. Claims 12-16 of 5965794 sets forth the transected plant cell is suspectable to the tobamovirus (TMV) for producing gene product, i.e., the movement protein, which meets the limitation of the instant claim 35. Thus, claims 11-16 of 5965794 are obvious variation over the instant claims 26, 28, 30 and 35 of the current application.

Claim 11 of 5965794 sets forth a method for introducing the transgene into the subject plant wherein introducing the transgene is done by known transformation (see column 7, line 50)

with growing the subject plant to an optimal condition prior to introducing the helper virus (see also column 7, lines 51-55). Thus, claim 11 of patent 6462255 is an obvious variation over the instant claim 27.

Claims 11 and 14 of 5965794 are obvious variation over claims 31-32 of the instant application since the invention of 5965794 is directed to the method of over expressing gene products in plants which include antisense RNA, ribozyme RNA, regulatory enzyme, structural protein, regulatory protein, or therapeutic protein wherein typical therapeutic proteins include members of the interleukin family of proteins and colony stimulating factors (see also column 7, lines 56-63).

Claims 11-16 of 5865794 disclose a functional movement protein encode by the sequence of the replicon upon which the helper virus depends (see also column 5, lines 26-28), which is the common subject matter set forth in claim 33 of the current application.

Since 5865794 disclosure sets forth that the replicon is capable of moving the replicon-encoded genes away from the site of infection and is also capable of systemic expression (see column 4, lines 64-67), claims 11-16 of 5865794 discloses the common subject matter of claim 36 of the current application.

Claims 11 and 14 of 5965794 are obvious variations over claim 34 of the instant application because claim 11 and 14 disclose that the helper virus depends upon the replicon and that the replicon encodes the movement protein which causes systemic expression of said replicon (see the patent claim 7 and abstract), which meets the limitation set forth in instant claim 34.

Therefore, the claims stated above in the instant application and those in US Pat. No. 5965794 discloses the same and/or common subject matter.

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. The terminal disclaimers signed by the assignee must fully comply with 37 CFR 3.73(b) with respect to the above rejections.

Claims 26-28 and 30-35 are rejected under the judicially created doctrine of the obviousness-type double patenting of claims 16-20 of US Pat. No. 5811653. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 16-20 of 5811653 and claims 26, 28 and 30 of the instant application disclose the common subject matter, i.e., a method of expressing a foreign product in plants comprising (a) integrating a transgene into a chromosome of a plant cell for transcribing the transgene comprising a replicon which comprises: a TMV-derived *replication origin* for replicating the replicon, and a foreign polynucleotide sequence (see claim 17), a helper virus (note that tobamovirus (TMV) is a single RNA virus wherein the RNA is plus strand RNA (see column 2, lines 41-42), and that the replicon is a RNA sequence generated from transcribing the transgene (see column 5, lines 59-65) with host RNA polymerase II (see column 7, lines 10-12)); (b) providing the plant cell with the a TMV-derived helper virus comprising a gene encoding a TMV-derived *replicase* that is necessary for the replicon function *via* infecting the plant with the

helper virus; and (c) producing the additional replicon component, i.e., the movement protein via translating the mRNA (i.e., the component of the replicon that is of RNA sequence) that directs synthesis of the movement protein (see the patent claim 16 and 18-20). The above disclosure of 5811653 meets all the limitation set forth in the application claims 26, 28 and 30. Since claim 16 also sets forth the transected plant cell is suspectable to the tobamovirus for producing gene product, i.e., the functional movement protein, which meets the limitation of the instant claim 35, claims 16 and 18-20 of 5811653 are obvious variation of claims 26, 28, 30 and 35 of the current application.

Claim 16 of 5811653 sets forth a method for introducing the transgene into the subject plant wherein introducing the transgene is done by known transformation (see column 7, line 38) with growing the subject plant to an optimal condition prior to introducing the helper virus (see also column 7, lines 42-44). Thus, claim 11 of patent 5811653 is an obvious variation over claim 27 of the instant application.

Also, claim 16 of 5811653 is an obvious variation over claims 31-32 of the instant application since the claimed invention of 5811653 is directed to the method of over expressing genes in plant (see abstract) wherein the gene products include antisense RNA, ribozyme RNA, regulatory enzyme, structural protein, regulatory protein, or therapeutic protein wherein typical therapeutic proteins include members of the interleukin family of proteins and colony stimulating factors (see also column 7, lines 45-49).

Claims 16 and 18-20 of 5811653 disclose a functional movement protein encoded by the sequence of the replicon upon which the helper virus depends (see also column 6, lines 55-58), which is the common subject matter set forth in claim 33 of the current application.

Further, claim 16 of 5811653 sets forth the replicon encodes the functional movement protein for which the helper virus does not encode and the function of the helper virus depends on the movement protein (see also column 6, lines 55-65 of 5811653), and because the invention of 5811653 is directed to the method for systemically infect a plant and systematically amplifying expression of the interest product (see the patent abstract and column 13, lines 37-38). Thus, claim 16 is an obvious variation over the instant claim 34.

Therefore, the claims stated above in the instant application and those in US Pat. No. 5811653 discloses the same and/or common subject matter.

It is noted that page 10 of the response filed 23 December 2003 requests abeyance of the obvious-type double patenting rejections over US Pat Nos. 5811653, 5889191, 6462255 and 5965794 until allowable subject matter is indicated. Note that no allowable subject matter can be indicated with a standing ground of rejections. Thus, it is suggested that applicants file the appropriate terminal disclaimers.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the

mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571-272-0949. The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low, can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

Karen Cochrane Carlson

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER

SWL

Samuel Wei Liu, Ph.D.

March 1, 2004